

# **EXHIBIT C**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

*All Cases*

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS  
TO MALLINCKRODT PLC**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure as well as the Case Management Order in *In re National Prescription Opiate Litigation* (Dkt. No. 232 in No.:17-cv-2804), Plaintiffs hereby requests that Defendant Mallinckrodt plc ("Mallinckrodt") respond to the following Requests for Production (the "Requests") in accordance with its obligations under the Federal Rules of Civil Procedure. Responses to the Requests shall be provided in the manner required by Rule 34(b)(2), the Local Rules of the Northern District of Ohio, the Court's Case Management Order One, filed April 11, 2018, Doc. No. 232, and any other applicable law or rules, within thirty (30) days of the service of these Requests.

If Mallinckrodt finds any term or other aspect of the Requests vague, ambiguous or otherwise objectionable and intend to so object, counsel for the Plaintiffs offer to promptly meet with counsel for Mallinckrodt to resolve any issues.

## **DEFINITIONS**

“You” or “Your” means Defendant Mallinckrodt plc, and its officers, directors, employees, partners, representatives, agents, divisions, predecessors or successors-in-interest, and other persons or entities acting on its behalf or controlled by it.

“Defendants” mean the named Defendants in the above-captioned matter.

“Plaintiffs” mean all the named Plaintiffs in the above-captioned matter.

“Document” is defined to be synonymous in meaning and equal in scope of the usage of this term in Fed. R. Civ. P. 34. A draft or non-identical copy is a separate document within the meaning of this term. In all events, the definition of “Document” shall include “Communications”, as defined below.

“Communication” means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise) and, with respect to oral communications, includes any document evidencing such oral communications. It includes the transmittal of information by any means, including email, SMS, MMS or other “text” messages, messages on “social networking” sites (including but not limited to, Facebook, Google+, MySpace, Instagram, Snapchat and Twitter), shared applications from cell phones, or by any other means. “Communication” also shall include, without limitation, all originals and copies that are provided by you or to you by others.

“Person” is defined as any natural person or any business, legal, or governmental entity, or association.

“Opioid” refers to that class of drugs, legal or illegal, natural or synthetic, used to control pain, including, but not limited to, the drugs referenced in Plaintiffs’ Complaint in the above-referenced matter.

“Opioid Products” refers to the Opioids that You and/or Your direct or indirect Subsidiaries developed, manufactured, marketed, promoted, sold, or distributed. This includes coatings, capsule configurations, delivery systems or mechanisms that include but are not limited to anti-abuse, tamper resistance and crush-proof mechanisms and mechanisms to deter immediate release. Opioid Products is also intended to include rescue medication for breakthrough pain. Opioid Products include both name-brand and generic products.

“Marketing” refers to the action or business of promoting, selling, or providing information about Opioids or Opioid Products. “Marketing” includes both branded and unbranded Communications; branded and unbranded informational or educational programs; detailing by sales representatives (including electronic detailing); continuing medical education; publication of scientific medical or marketing articles, Scientific Research, studies or reports; websites (whether branded or unbranded); video or other visual media; sales blasts, messages, or other means used to sell or promote Opioids or Opioid Products for sale or distribution.

“Branded Marketing” refers to Marketing which identifies and promotes a specific drug.

“Unbranded Marketing” is Marketing that does not refer to a specific drug, but more generally to a disease state or treatment.

“Adverse Event” shall be as defined by the FDA and shall mean and include any undesirable experience associated with the use of a drug in a patient.

“Suspicious Order” shall be as defined by the DEA and shall include, but not be limited to, orders for Opioids or Opioid Products of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

“Scientific Research” includes studies, investigations, trials, articles, comparisons, case histories, reviews, reports, or analyses that are conducted by doctors, researchers, or other investigators.

“DEA Quotas” mean aggregate, manufacturing, and procurement quotas established pursuant to 21 U.S.C. § 826 in accordance with 21 CFR 1303.11.

“Subsidiary” means any corporation, partnership, limited liability company, association, trust or other form of legal entity of which Covidien PLC or Mallinckrodt plc owned at any time, directly or indirectly, securities or other equity interests representing more than 25% of the aggregate voting power thereof or more than 25% of the aggregate equity interest therein.

“Mallinckrodt Entity” means each of Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt LLC, and each entity that is a Subsidiary of any of Mallinckrodt plc, Mallinckrodt International Finance S.A., or Mallinckrodt LLC.

### **INSTRUCTIONS**

The time period covered by these Requests for Production is one year prior to the launch of each relevant Opioid Product through the date of Your response, unless otherwise specified, or as specified in rulings by the Court or Special Master, whichever period is longer.

All ESI shall be produced in its original native form, including all metadata, and shall be subject to the provisions of the agreed-upon ESI protocol.

All video and audio files must be produced in the manner in which you store and retrieve them, *i.e.*, in their native formats and shall be subject to the provisions of the agreed upon ESI protocol.

### **REQUESTS FOR PRODUCTION**

**REQUEST FOR PRODUCTION NO. 1:** Documents that reflect Your corporate organizational structure and governance, and how You are structured to oversee and manage Your global operations with regard to the development, testing, regulatory approval, manufacture, branding, marketing, sale, promotion, distribution suspicious order monitoring and pharmacovigilance relating to Your generic and name-brand pharmaceutical drug products, including Opioid Products.

#### **RESPONSE:**

**REQUEST FOR PRODUCTION NO. 2:** Documents that reflect Your global corporate branding and marketing plans and efforts to market Your pharmaceutical drug products under the “Covidien” or “Mallinckrodt” name, and the identity of the Persons and departments responsible for corporate branding.

#### **RESPONSE:**

**REQUEST FOR PRODUCTION NO. 3:** Documents that reflect the identity, roles and operations of Your Subsidiaries (including direct and indirect Subsidiaries) involved in the development, testing, regulatory approval, manufacture, branding, marketing, sale, promotion, distribution, suspicious order monitoring or pharmacovigilance relating

to Your generic and name-brand pharmaceutical drug products, including Opioid Products, and Your corporate relationship to those Subsidiaries.

RESPONSE:

REQUEST FOR PRODUCTION NO. 4: Documents that reflect the manner in which You monitor, oversee, direct and control Your Subsidiaries (including direct and indirect Subsidiaries) with regard to the development, testing, approval, manufacture, marketing, sale, promotion, distribution, suspicious order monitoring or pharmacovigilance relating to Your generic and name-brand pharmaceutical drug products, including Opioid Products. This includes Documents reflecting any meetings, reports, audits, directives, recommendations and other communications between You and Your Subsidiaries.

RESPONSE:

REQUEST FOR PRODUCTION NO. 5: Documents that reflect the identity of Your employees, officers, agents, or representatives who are involved in the development, testing, approval, manufacture, marketing, sale, promotion, distribution, suspicious order monitoring or pharmacovigilance relating to Your generic and name-brand pharmaceutical drug products, including Opioid Products, including documents sufficient to identify where geographically each identified person conducts his or her work.

RESPONSE:

REQUEST FOR PRODUCTION NO. 6: Documents that reflect the identity including the location, description and ownership of any of Your or any direct or indirect Subsidiary's plant, property and equipment in the United States.

RESPONSE:

REQUEST FOR PRODUCTION NO. 7: Documents that reflect the manner in which decisions have been and continue to be made to hire or terminate Your employees in the United States, including but not limited to the employees of Your direct and indirect Subsidiaries.

RESPONSE:

REQUEST FOR PRODUCTION NO. 8: Documents that reflect the manner in which decisions have been and continue to be made as to how Your direct and indirect Subsidiaries are to work together with regard to the development, testing, regulatory approval, manufacture, branding, marketing, sale, promotion, distribution, regulation or compliance, suspicious order monitoring or pharmacovigilance relating to Your generic and name-brand pharmaceutical drug products, including Opioid Products, and how those decisions are implemented.

RESPONSE:

REQUEST FOR PRODUCTION NO. 9: Documents that reflect the manner in which budgets are created for You and Your direct and indirect Subsidiaries, and how those Subsidiaries are financed, the manner in which their funds are held, the extent to



which their funds are commingled, what entity controls their financial accounting, how financial books and records are kept, and the identity of any and all financial accountants or accounting firms retained with regard to accounting for those funds.

RESPONSE:

REQUEST FOR PRODUCTION NO. 10: Documents that reflect the identity of Your Board of Directors and the composition and responsibilities of any Board committees, task forces, or working groups comprised of Board members related to Your generic and name-brand pharmaceutical drug products, including Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 11: All Annual Reports or similar reports filed with US or Irish or United Kingdom regulators.

RESPONSE:

REQUEST FOR PRODUCTION NO. 12: To the extent such departments exist, Documents that reflect the structure of Your marketing and sales departments for Your generic and name-brand pharmaceutical drug products (including Opioid Products), including divisions within each department (*i.e.* regional/segment/area divisions for sales and marketing).

RESPONSE:

REQUEST FOR PRODUCTION NO. 13: To the extent such departments exist, Documents that reflect the job responsibilities for each position in Your sales and marketing departments, and any compensation structure that is based in whole or in part on levels of sales of Your generic and name-brand pharmaceutical drug products, including Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 14: Documents that reflect Your involvement in the manner in which You or Your direct or indirect Subsidiaries market, price and sell Your generic and name-brand pharmaceutical drug products, including Opioid Products, globally including in the United States. Include how you develop and implement global brand, marketing and pricing plans for the sale of Your products, the persons and departments involved in developing those plans, and implementation and reporting structure for these plans between Mallinckrodt plc and its direct and indirect Subsidiaries.

RESPONSE:

REQUEST FOR PRODUCTION NO. 15: To the degree that such departments exist, Documents that reflect the structure of Your regulatory, manufacturing, distribution and compliance departments for Your generic and name-brand pharmaceutical drug products (including Opioid Products), including divisions within each department (*i.e.* regional/segment/area divisions for sales and marketing).

RESPONSE:

REQUEST FOR PRODUCTION NO. 16: Documents that reflect Your involvement in the manner in which You or Your direct or indirect Subsidiaries develop, manufacture and distribute Your generic and name-brand pharmaceutical drug products, including Opioid Products, globally including in the United States, including but not limited to how you develop and implement global development, manufacturing and distribution plans for Your products, the Persons and departments involved in developing those plans, and the reporting structure for these plans.

RESPONSE:

REQUEST FOR PRODUCTION NO. 17: Documents that reflect Your policies and procedures concerning the branding, marketing, sale, promotion, distribution of Your generic and name-brand pharmaceutical drug products, including Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 18: Documents that reflect Your policies and procedures concerning regulatory, pharmacovigilance and drug safety, and compliance with regulations and conditions concerning the sale, marketing and distribution of Your generic and name-brand pharmaceutical drug products, including Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 19: Documents that reflect your policies and procedures as to how You manage your global operations and that concern or affect your operations in the United States concerning internal accounting, internal and external audits, directives from You to Your direct or indirect Subsidiaries, and reporting back by a Subsidiary to You on the Subsidiary's operations.

RESPONSE:

REQUEST FOR PRODUCTION NO. 20: Documents that reflect your policies and procedures with regard to personnel management, including but not limited to hiring, promotion, termination and reviews.

RESPONSE:

REQUEST FOR PRODUCTION NO. 21: Documents that reflect surveys, focus groups, market research or other similar research or investigation that You performed, had performed on Your behalf, or that you received or reviewed, regarding physician or public perceptions of the safety, efficacy and/or addictive nature of Your Opioid Products, other Opioid products, or Opioids and Your use of focus groups, research or investigations in developing a sales and marketing strategy and/or a strategy on how to effect, change or influence those perceptions.

RESPONSE:

REQUEST FOR PRODUCTION NO. 22: Documents that reflect the role of wholesalers, distributors, pharmacies, hospitals, formularies, and government entities,

agencies and departments (including any other defendants) in the supply chain for Your and/or Your direct or indirect Subsidiaries' Opioid Products and the responsibilities of each with respect to Marketing, sales, supply, Suspicious Order monitoring and potential diversion.

RESPONSE:

REQUEST FOR PRODUCTION NO. 23: Documents that reflect reports or the like that were given to the Board of Directors regarding Your generic or name-brand pharmaceutical drug products, including Opioid Products, for the United States, including but not limited to reports regarding:

- a. Sales;
- b. Lobbying efforts;
- c. Safety and efficacy of Opioids or Your Opioid Products;
- d. Submissions to the FDA or DEA;
- e. Documents, studies, reports, data or other information that You did not submit to FDA or DEA;
- f. Abuse potential for Opioids or Your Opioid Products;
- g. Reports of abuse, misuse, diversion, addiction or dependence regarding Opioids or Your Opioid Products;
- h. Government investigations regarding Opioids or Your Opioid Products;
- i. Sales and marketing of Opioids or Your Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 24: Documents that reflect Your annual sales, revenue, profits and market share for and the identity of each Opioid Product sold in the United States.

RESPONSE:

REQUEST FOR PRODUCTION NO. 25: Documents that reflect any meetings, correspondence, communications, documents, contracts or agreements, between You and Purdue, Janssen, Endo, and Teva (and any of their predecessor or successor companies, Subsidiaries or affiliates), concerning the manufacture, development, formulation, marketing, advertising, sale and distribution of generic and name-brand pharmaceutical drug products, including Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 26: Documents that reflect financial and business arrangements with any of the Defendants in this matter including any contractual relationships between You and any of the Defendants in this matter.

RESPONSE:

REQUEST FOR PRODUCTION NO. 27: Documents that reflect Communications between You (Mallinckrodt plc) and any of Your direct or indirect Subsidiaries concerning the development, regulatory approval and regulatory matters, branding, marketing, sale, promotion, distribution and suspicious order monitoring concerning Opioid Products in the United States.

RESPONSE:

REQUEST FOR PRODUCTION NO. 28: Documents that reflect Communications by and between Your and/or Your direct or indirect Subsidiaries' employees concerning the development, regulatory approval, marketing, sale, promotion, distribution and suspicious order monitoring concerning Opioid Products in the United States.

RESPONSE:

REQUEST FOR PRODUCTION NO. 29: Documents that reflect Your and/or Your direct or indirect Subsidiaries' global brand, marketing and sales plans concerning Your generic and name-brand pharmaceutical drug products, including Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 30: Documents that reflect Your market research, analysis or projections concerning the generic pharmaceutical drug market, including for Opioid Products, in the United States.

RESPONSE:

REQUEST FOR PRODUCTION NO. 31: Documents that reflect performance reviews conducted by You (Mallinckrodt plc) of the officers, and of department heads for Your direct or indirect Subsidiaries to the extent any of their departments were involved

in the marketing, sale, promotion, distribution and suspicious order monitoring for Opioid Products.

RESPONSE:

REQUEST FOR PRODUCTION NO. 32: Documents relating to the July 2017 agreement between DEA, DOJ, and You and Mallinckrodt LLC.

RESPONSE:

REQUEST FOR PRODUCTION NO. 33: All Documents governing, setting forth the terms of, relating to, filed with any governmental agency in connection with, or provided to the members or shareholders of any entity providing notice or soliciting support of, the Transactions, as defined in that certain Form 8-K filed by Mallinckrodt Public Limited Company with the United States Securities and Exchange Commission dated June 28, 2013 (SEC Accession No. 0001193125-279760) (the "Form 8-K"), including, without limitation, the following (including all amendments and modifications thereto):

- a. The Separation and Distribution Agreement between Mallinckrodt plc and Covidien Public Limited Company dated June 28, 2013 (the "Separation and Distribution Agreement"), including all (i) exhibits, schedules, appendices and attachments thereto, and (ii) instruments, certificates and opinions executed or rendered in connection therewith or evidencing the satisfaction of and condition provided for therein;
- b. All additional documents listed as Exhibits to the Form 8-K;



- c. All documents identifying “Excluded Assets” as that term is used in the Separation and Distribution Agreement;
- d. All documents identifying “Excluded Liabilities” as that term is used in the Separation and Distribution Agreement;
- e. The “Form 10” as that term is used in the Separation and Distribution Agreement;
- f. The “Information Statement” as that term is used in the Separation and Distribution Agreement;
- g. All documents identifying “Mallinckrodt Accounts” as that term is used in the Separation and Distribution Agreement;
- h. All documents identifying “Mallinckrodt Assets” as that term is used in the Separation and Distribution Agreement, including, without limitation, the “Transferred Entities” as such term is used in the Separation and Distribution Agreement;
- i. All documents identifying “Mallinckrodt Liabilities” as that term is used in the Separation and Distribution Agreement.

RESPONSE:

REQUEST FOR PRODUCTION NO. 34: All reports on Form 10-K or Form 10-Q filed with the United States Securities and Exchange Commission of (i) Covidien Public Limited Company (“Covidien PLC”) for periods ending December 31, 2013 or prior; or (ii) Mallinckrodt plc.

RESPONSE:

REQUEST FOR PRODUCTION NO. 35: All annual reports provided by Covidien PLC for years ending in 2013 or prior, or by Mallinckrodt plc at any time, to its members or shareholders.

RESPONSE:

REQUEST FOR PRODUCTION NO. 36: Documents sufficient to identify all intercompany transactions involving any two or more Mallinckrodt Entities, including, but not limited to, cash transfers, property, tangible or intangible assets transfers, investments in consolidated and non-consolidated affiliates, assumption of liabilities and lease agreements.

RESPONSE:

REQUEST FOR PRODUCTION NO. 37: All Documents evidencing any distribution, dividend or other payment or transfer (collectively, an “Intra-corporate Transfer”) (i) received by Covidien PLC from any Subsidiary on or prior to December 31, 2013, or (ii) received by Mallinckrodt plc at any time from any Subsidiary.

RESPONSE:

REQUEST FOR PRODUCTION NO. 38: All documents evidencing or containing any analysis or assessment of: (i) whether after any Intra-corporate Transfer, the Subsidiary making such Intra-corporate Transfer would be left with “unreasonably small capital” as such term is used in Section 548 of the United States Bankruptcy Code; (ii)

whether after any Intra-corporate Transfer, the Subsidiary making such Intra-corporate Transfer would be unable to pay its obligations as they became due.

RESPONSE:

REQUEST FOR PRODUCTION NO. 39: For each Mallinckrodt Entity, (i) year-end balance sheets for each such Mallinckrodt Entity for each year ending during 2009 through 2018, , (ii) statements of income for each such Mallinckrodt Entity for each year ending during 2009 through 2018, (iii) statements of cash flows for each such Mallinckrodt Entity for each year ending during 2009 through 2018, (v) statements of changes in shareholders' equity for each such Mallinckrodt Entity for each year ending during 2009 through 2018, and (vi) general ledgers for each such Mallinckrodt Entity as maintained during each of 2009 through 2018.

RESPONSE:

REQUEST FOR PRODUCTION NO. 40: Provide each United States Patent held by any Mallinckrodt Entity at any time since June 28, 2013 and each current pending patent application, and identify the Mallinckrodt Entity that is the holder of each issued or applied for patent.

RESPONSE:

REQUEST FOR PRODUCTION NO. 41: Documents evidencing or summarizing all Mallinckrodt plc business related travel to the United States by any officer, director, employee or agent of Mallinckrodt plc from June 28, 2013 to the present.

RESPONSE:

REQUEST FOR PRODUCTION NO. 42: Every guarantee or other assurance of payment given by any Mallinckrodt Entity to any third party by with respect to any obligation or liability of any other Mallinckrodt Entity.

RESPONSE:

DATED this 25th day of January, 2019.

**KELLER ROHRBACK L.L.P.**

By /s/Dean Kawamoto

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this January 25, 2019, the foregoing has been served via email to Defendants' Listserv: xALLDEFENDANTS-MDL2804-service@arnoldporter.com.

s/ Dean Kawamoto

Dean Kawamoto